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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,443	KOTANI ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69 and 92-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69 and 92-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/27/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's remarks filed on January 27, 2010 have been entered. Claims 69 and 92-94 are pending and under examination.

Response to Amendment

2. The following objection and rejection are withdrawn:

- The objection to claims 92 and 94 for a typographical error is withdrawn in view of Applicant's amendment.
- The rejection of claims 69 and 92-94 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in favor of a scope of enablement rejection set forth below. Applicant's arguments are addressed in the new rejection.

Claims Summary and Interpretation

3. Claims 1 and 92 are drawn to a method for inhibiting tumor cell growth in an animal by administering a composition that *consists essentially of* a hemagglutinating virus of Japan (HVJ) viral envelope (HVJ-E), wherein IL-12 and IL-16 in dendritic cells are induced or regulatory T cells are inhibited. Chapter 2111.03 of the MPEP [R-3] provides guidance on the use of transitional phrase "consisting essentially of" as it defines the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of

the claimed invention. Thus Applicant's composition does not contain any other component that interferes with the ability of HVJ-E to inhibit tumor cell growth.

Claims 93 and 94 are drawn to a method for inhibiting tumor cell growth in an animal by administering a composition that *consists of* a hemagglutinating virus of Japan (HVJ) viral envelope (HVJ-E) and a pharmaceutically acceptable carrier, wherein IL-12 and IL-16 in dendritic cells are induced or regulatory T cells are inhibited.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69 and 92-94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting tumor cell growth in an animal via intratumoral administration of the envelope protein of HVJ, does not reasonably provide enablement for any administration outside of the scope of intratumoral administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The breadth of the claims is drawn to a method for inhibiting tumor cell growth *in vivo* by administering a composition consisting essentially of HVJ-E, or consisting of HVJ-E and a carrier, via any route of administration.

The state of the art, as pointed out by Applicant in the remarks filed January 27, 2010, shows that the HVJ-E protein is capable of inhibiting tumor growth when administered

intratumorally. In Kurooka & Kaneda (2007), Fujihara *et al.* (2008) and Kawaguchi *et al.* (2009), (all submitted with the IDS filed 1/27/2010), the mode of administration was intratumoral. There is no evidence of other routes of administration having the claimed effect of inhibiting tumor growth *in vivo*.

The specification shows that the administration of HVJ-E alone inhibits growth of tumor cells when administered intratumorally (see specification, pages 29 and 30, for example). In the declaration of Toshihiro Nakajuma, filed under 37 CFR 1.132 on January 27, 2010, intratumoral injections of HVJ-E are also shown to inhibit tumor growth. Again, there is no evidence of *in vivo* inhibition of tumor growth via other routes of administration besides intratumoral. One of skill in the art would not reasonably expect any degree of remission from intravenous or oral administration absent evidence of some type of *in vivo* data.

Therefore, in view of the breadth of the claims, the state of the art, and the teachings in the specification, it would require undue experimentation to practice the claimed method of inhibiting tumor cell growth with HJV-E via any route of administration other than intratumoral.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(*Reinstated Rejection*) Claims 69 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneda (EP 1170363 A1, filed in IDS of 12/20/06), upon further consideration of

the art and the claim language. The claims are summarized above. Kaneda discloses virus envelope vectors from HVJ for gene transfer (see abstract and paragraphs [0011-0012]). Kaneda discloses that the vector is capable of gene transfer into a broad range of *in vivo* tissue, including cancer tissue (see paragraph [0012]). Kaneda administers the HVJ envelope vector comprising a luciferase gene into a squamous cell carcinoma on a human tongue (see page 13, paragraph [0116]). Kaneda's HVJ-E and luciferase gene construct qualifies as a composition consisting essentially of HVJ-E because the luciferase gene, a marker of expression, does not interfere with the anti-tumor capabilities of HVJ-E. Further, although Kaneda does not specifically appreciate that the HVJ-E/luciferase gene construct will inhibit the carcinoma, it is expected to have this effect because the construct is the same as that instantly claimed. In another example, Kaneda administers a HVJ-E/pCMV-luciferase construct to a tumor mass of mouse melanoma (see paragraph [0140], Example 16). The pCMV-luciferase component of the construct is understood by the Office to fall within the scope of "consisting essentially of HVJ-E" because the pCMV and luciferase are not anti-tumor inhibitors, but merely a promoter for the luciferase, which is itself a marker of expression. Any functional properties of the instant vector are expected to be present in Kaneda's vector, including the effect of inducing IL-12 and Il-6 in dendritic cells or inhibiting regulatory T cells, thus the method is expected to accomplish the same functions instantly claimed.

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that Kaneda discloses the use of HVJ-E as a gene transfer vector for introducing a foreign gene, thus the construct comprises more than HVJ-E because it also comprises a foreign gene.

For this reason, Applicant argues that Kaneda's disclosure is outside the scope of the instantly claimed method that uses a composition consisting essentially of HVJ-E as an active ingredient.

In response to Applicant's arguments, the transitional phrase "consists essentially of" indicates that the composition contains HVJ-E as an active ingredient for inhibiting tumor cell growth in an animal, and no other component is present that inhibits tumor cell growth. The composition may contain any other component that does not inhibit tumor cell growth or interfere with the anti-tumor properties of HVJ-E.

Applicant also argues that Kaneda does not teach a method for inhibiting tumor cell growth by administration of HVJ-E because Kurooka & Kaneda (published in 2001, after the Kaneda reference, shared authors), assert that theirs "is the first report to show that HVJ-E alone can eradicate tumors". Applicant argues that this statement shows that the authors of the Kaneda reference did not recognize the ability of HVJ-E alone to inhibit tumors.

In response to Applicant's arguments, the fact that Kaneda did not recognize the ability of their vectors to inhibit tumor cell growth does not change the fact that Kaneda administered a construct consisting essentially of HVJ-E/luciferase or HVJ-E/pCMV-luciferase to a malignant tumor. In other words, Kaneda administered the same composition to the same patient population. The result is expected to be the same: inhibition of tumor growth. Therefore, the invention remains anticipated by Kaneda.

Conclusion

6. No claim is allowed. This action is made non-final in view of the new grounds of rejection set forth above.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648